

REMARKS

**Status of the claims**

Claims 1-55 were pending in the subject application, yet only claims 1-39 were under active consideration. No claims have been canceled or newly added with this submission. However, claims 3, 4, and 18 have been amended. Therefore, upon entry of this Response, claims 1-55 will remain pending of which claims 1-39 will be under active consideration.

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

**Claim objections**

Claims 3 and 4 are objected to for the term “collection duct,” which the Examiner alleges may be confused with the same term in claim 1 but referring to a different element of the claimed device. Applicants have deleted reference to a “collection duct” in both claim 3 and 4 in favor of a “direct” connection between the device and the collection needle. Support for this amendment may be found at least at page 17, paragraph 0071, last sentence.

Claim 19 is also objected to because the Examiner believes that the recited biochips may be interpreted to comprise analytes, whereas “it appears from the [] disclosure that the analyte is not part of the biochip but rather the biochip is intended for capturing an analyte.” Applicants respectfully note, however, that “analyte,” within the meaning of the instant application, does in fact refer to a reagent on the biochip used to capture and detect molecules in test specimen. *See, e.g.*, page 9, paragraph 0044. The molecules in the test specimen are defined as “target agents” in the instant application. Hence, claim 19 should be construed to encompass biochips comprising analytes.

Applicants thank the Examiner for her careful reading of the claims and respectfully submit that the objections to the claims have been overcome.

### **Claim rejections under 35 USC § 112, second paragraph**

Claim 17 stands rejected for the term “low density,” which is alleged to be indefinite. The Examiner alleges that “the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.” Applicants respectfully traverse this rejection because, in fact, “low density” is defined as “microarrays of less than 100 analytes” in the last sentence of page 9. Hence, Applicants respectfully submit that the term “low density” is sufficiently definite to particularly point out and distinctly claim the invention. Withdrawal of the rejection is respectfully solicited.

### **Claim rejections under 35 USC § 103(a)**

Claims 1-6, 10-17 and 22-39 stand rejected under 35 USC § 103(a) for alleged obviousness over USP 6,924,107 to Liu (“Liu”). The reasons for the rejection are reported on pages 3-11 of the outstanding Office Action. Applicants respectfully traverse the rejection on the following grounds.

The claimed invention comprises chambers “through which the blood flows are designed to have a cross-sectional area that is no smaller than that of the collection duct.” This feature is designed to minimize any reduction in blood flow though the claimed device. The device of Liu, however, is contrastingly designed so that the volume of sample moving through the device *is* reduced and then to “control” consistent reduced flow through the device. This feature of the Liu device is repeatedly stressed. *See, e.g.*, col. 8, ln 58-63, col. 9, ln 60-63; col. 10, ln 21-22; col. 12, ln 1-4. Hence, at best, Liu teaches *away* a device with chambers having “a cross-sectional area that is no smaller than that of the collection duct.”

The Examiner appears to agree that Liu is deficient in this regard, yet asserts that the “general condition” of the claimed element are disclosed and that discovering the optimum or workable ranges involves only routine skill in the art. Applicants respectfully disagree.

It is respectfully noted that the present invention is designed such that “a flow rate of blood flowing through the [device] is *roughly equal* to the flow rate of collected blood in the absence of the [device].” Page 8, last sentence (emphasis added). Liu, in contrast, extols the virtue of a device that uses “small diameter capillaries” to reduce and control flow rates. In no event does Liu teach flow rates through its devices “roughly equal” to flow rates achieved in the absence of same. In fact, Liu acknowledges that reducing flow volume is germane to the operation of its device—higher effective hybridization for more complete hybridization and a higher hybridization rate, which reduces the amount of probe solution required to perform the assay. Col. 9 ln 66 – col. 10, ln 3. Hence, it cannot have been obvious to modify the teachings to Liu in a manner that would *increase* flow rate through Liu’s device, namely, by incorporating chambers having “a cross-sectional area that is no smaller than that of the collection duct.” Such a modification would be antithetical to the very teaching of Liu, because Liu “teaches away” from such a design, namely a device incorporating chambers “through which the blood flows are designed to have a cross-sectional area that is no smaller than that of the collection duct.”

Applicants also note that the claimed device is suitable for use in in-line screening of blood, while Liu’s device is *not*. For instance, Liu discloses no pumping mechanism and no system for drawing blood from a needle inserted into a donor, through a collection duct and screening capture device, and into a blood collection container. Ostensibly most telling is that fact that Liu does not even mention the word “blood” in its disclosure. In short, the Examiner’s “modification” of Liu’s device (*e.g.*, into a “high” flow, blood sampling device) would render Liu’s device unsatisfactory for its intended purpose (*i.e.*, high throughput screening of *prepared* samples. *See, e.g.*, col. 3, ln 44-54). Such an interpretation of the art to establish a *prima facie* case of obviousness is impermissible. MPEP 2143.01(V). Thus, Applicants respectfully request the withdrawal of the subject rejection.

Claims 7-9, 19 and 21 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Liu in view of USP 6,020,209 to Narang, *et al.* (“Narang”). Claim 20 stands rejected under the same statute as allegedly unpatentable over Liu in view of US 2001/0053535

to Bashir *et al.* (“Bashir”) in further view of US 2003/0134416 to Yamanishi, *et al.* (“Yamanishi”). Applicants respectfully submit that these secondary references fails to cure the deficiencies of the primary references as noted above. Accordingly, Applicants respectfully solicits withdrawal of the rejections for obviousness.

**Allowable subject matter**

Applicants thank the Examiner for indicating that claim 18 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have rewritten claim 18 in independent form.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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